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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/761,116	01/16/2001	Vedrana S. Susulic	0630-1E791-US1	3094

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EXAMINER

LEFFERS JR, GERALD G

ARTICLE PAPER NUMBER

1636

DATE MAILED: 01/14/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/761,116

Applicant(s)

SUSULIC ET AL.

Examiner

Gerald G Leffers Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29 and 34 is/are allowed.
- 6) ☒ Claim(s) 28, 30-33, 35-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Receipt is acknowledged of an amendment, filed 10/16/02 as Paper No. 11, in which several claims were cancelled (claims 1-2, 22-27), claims were amended (claims 28-30, 33-34) and new claims were added (claims 38-39). Claims 28-39 are pending in the instant application.

Because new grounds of rejection are raised in the instant action that were not necessitated by applicants' amendment of the claims in Paper No. 11, the instant action is not final.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28, 31-33, 36-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection.**

The rejected claims are directed to methods of screening for a compound that increases or decreases the activity of an Sp1 or B segment-binding B₃-adrenergic receptor (B₃-AR) transactivating factor in human cells wherein cells expressing at least one of the two recited factors are contacted with a test compound and an increase or decrease "in a level of activity" for the recited factor. The phrase "in a level of activity" encompasses literally any activity that may be associated with Sp1 or the B segment-binding B₃-adrenergic receptor transactivating factors.

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Sp1 is known in the art to be associated with the regulation of a number of different genes in vivo in response to different cellular conditions. The instant specification describes Sp1 activity only in relation to expression of the B₃-adrenergic receptor gene. The B segment-binding B₃-adrenergic receptor transactivating factor is characterized in the instant specification only with regard to the B₃-adrenergic receptor. This activity is not described anywhere else in the prior art. There is no basis in the instant specification or prior art for one of skill in the art to envision a representative number of activities associated with the two recited transcription factors sufficient to describe the entire broadly claimed genus of such activities. Therefore, one of skill in the art would reasonably conclude that applicants were not in possession of the claimed invention. It would be remedial to explicitly link the detection of Sp1 or B segment-binding B₃-adrenergic receptor transactivating factor activities to B₃-adrenergic receptor gene expression.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30, 35, 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30 and 35 are vague and indefinite in that the end result of the claim does not necessarily match the preamble of the claim. **This is a new rejection.** The rejected claims are directed to methods of screening for a compound that increases or decreases the activity of an Sp1 or B segment-binding B₃-adrenergic receptor (B₃-AR) transactivating factor in human cells

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wherein cells expressing at least one of the two recited factors are contacted with a test compound and an increase or decrease activity for the recited factor is detected by determining the amount of the recited transcription factor in the cells. The level of the recited transcription factor in the cell does not necessarily correlate to the level of activity for the transcription factor. For example, the level of the transcription factor in the cell may be far higher than that required for expression of the B₃-adrenergic receptor gene. Alternatively, an increase in the level of the transcription factor would not result in an increase of its activity if the additional transcription factor were inactive. Moreover, upon reading the specification, it appears that the limitation for these dependent claims may be intended to specify one detects an increase or decrease in transcription factor activity by detecting the level of the gene product for the target gene for these transcription factors (i.e. the B₃-AR gene).

Claim 31 is vague and indefinite in that the metes and bounds of the term "express at very low level, B₃-AR" are unclear. **This rejection is maintained for reasons of record in Paper No. 10, mailed 7/16/02 and repeated herein.** How much of B₃-AR can be expressed by the cell for it to remain at a "very low level". This concept does not appear to be defined clearly in the specification and should be deleted from the claim language.

Claims 38 and 39 are vague and indefinite in that there is no clear and positive prior antecedent basis for the phrases "the sequence that is greater than 80% identical to the nucleotide sequence" and "the Sp1-binding site". **This is a new rejection.**

Conclusion

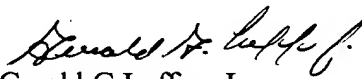
Claims 28, 30-33, 35-39 are rejected. Claims 29 and 34 are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Gerald G Leffers Jr.
Examiner
Art Unit 1636

Ggl
January 10, 2003